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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/513,910	02/25/2000	Jeffrey Burbank	9313.16739-1	7072
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PROSKAUER ROSE LLP PATENT DEPARTMENT 1585 BROADWAY NEW YORK, NY 10036-8299			EXAMINER BIANCO, PATRICIA	
			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 12/10/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Caton's Secretary
↳ Candy

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Office Action Summary	Application No. 09/513,910	Applicant(s) BURBANK ET AL.	
	Examiner Patricia M Bianco	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15, 20 and 29-43 is/are pending in the application.
 4a) Of the above claim(s) 13, 15 and 20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-12 and 29-36 is/are allowed.
- 6) ☒ Claim(s) 1-5 and 37-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <i>Final Rejection</i> . |

DETAILED ACTION

Response to Amendment

1. **Claims 1-13, 15, 20 & 29-43 are currently pending.**

The amendment filed July 14th, 2003 presented the following amendments: portions of the specification and drawings were amended to correct informalities; claims 6, 9, 13, 15, 29, & 32 were amended; claims 14, 16-19, & 21-28 were cancelled; and new claims 37-43 were added.

Applicant also filed a supplemental declaration to overcome the outstanding objection to the originally filed declaration. However, the new declaration does not include a claim for priority under 35 USC 120.

Applicant also asked for reconsideration and rejoinder of amended claims 1-5, 13, 15, 20 and newly presented claims 37-43. After reconsideration, it is agreed that amended claims 1-5 are directed to the elected invention of Group II, however, claims 13, 15 & 20 remain directed to a different invention (Group III). The invention of claims 13, 15 & 20 further require a hemofiltration system having a hemofiltration machine including a chassis and a controller for operation of the system. Therefore, they have not been rejoined.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When

Art Unit: 3762

claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 41-44 (presented in the amendment filed July 14th, 2003) have been **renumbered 40-43** to preserve the numbering of claims presented.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior co-pending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

The section requesting priority under 35 USC 120 is missing from the original and substitute declarations. Applicant indicates in the first paragraph of the

Art Unit: 3762

specification that the instant application was filed as a CIP of 08/800,881 and as a DIV of 09/451,238.

Election/Restrictions

4. Applicant's election of Group II, claims 6-12 & 29-36 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-5, and newly presented claims 37-43, have been rejoined with Group II and examined on the merits at this time.

5. Claims **13, 15 & 20 remain withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 3762

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.


Claim 43 recites the limitation "at least one bag spike" as part of the replacement fluid line, recited in line one of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

 Claims 1-4 & 37-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Polaschegg et al. (7,702,829). Polaschegg et al. (hereafter Polaschegg) discloses a hemodiafiltration system including an extracorporeal circuit which circulates blood from an individual through a hemofilter such that waste is removed, replacement fluid is added to the blood downstream of the filter, and the combined waste-free blood and replacement fluid is returned to the patient. The extracorporeal circuit includes a replacement fluid path, shown in the figure as line 90, tubing 94, and connectors 100 & 116. The replacement fluid circuit further includes a microfilter (98), which is integral with the line and tubing for removing pyrogens from the replacement fluid. The dashed lines in the figure also define the replacement fluid circuit. The replacement fluid may be added to the treated blood at location 116. (See col. 5, line 36-col. 6, line 50). The

Art Unit: 3762

claim limitations that the extracorporeal circuit "for circulating blood....through a hemofilter to remove waste..." and of the replacement fluid path "to convey replacement fluid from a source to the extracorporeal circuit" in claims 1 & 6 have been treated as intended use recitations. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Since neither the hemofilter nor source has been positively claimed, it is the position of the examiner that the circuits in the system of Polaschegg are capable of connecting to a hemofilter and to a source.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 3762

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims **5 & 43 are rejected** under 35 U.S.C. 103(a) as being unpatentable over Polaschegg et al. ('829). Polaschegg et al. discloses the invention substantially as claimed, however fails to disclose specifically that the microfilter includes a 0.2 micron filter medium and fails to disclose specifically that the replacement fluid line has at least one bag spike. It is well known in the medical art to use fittings to connect tubing to containers holding medicinal fluids wherein the fitting includes a bag spike so that a source of fluid may be accessed. Therefore, it would have been obvious to one having skill in the art at the time of the invention to modify the system of Polaschegg to include a line that includes a bag spike such that the line may be connected to a source of replacement fluid or components thereof. Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to choose the microfilter medium to be a 0.2 micron filter medium as a preferred material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Allowable Subject Matter

10. Claims **6-12 & 29-36** are allowed.

With respect to claims 6 & 29, as well as their respective dependent claims, the subject matter not found was the waste fluid being the only fluid contacting the waste or filtrate side of the hemofilter with no fluid entering the waste side in combination with the other limitations or steps of the claims.

With respect to claim 32, the subject matter not found was the step of subjecting the extracorporeal circuit to refrigeration between multiple intermittent sessions in combination with the other limitations of the claims.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3762

12. Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9306 for regular and After Final communications.

Tricia Bianco
Patent Examiner
Art Unit 3762

pmb 
November 14th, 2003